IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: *All Wave 7 cases listed in Exhibit A to Defendants' motion*	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

The Plaintiffs respectfully request that this Court deny Defendants' motion that seeks to limit Dr. Bruce Rosenzweig's general opinions for the Wave 7 cases.

INTRODUCTION

Dr. Rosenzweig's opinions have been vetted as much as any expert's in the various MDLs. This Court has consistently found him well qualified to testify on a wide variety of topics. This Court has written, in various *Daubert* orders, that "Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body"; that "[a]lthough Dr. Rosenzweig has never designed vaginal mesh devices, he has considerable familiarity with their structure and use"; that "Dr. Rosenzweig received thorough training on the implantation of sling products in pelvic repair"; and that "although Dr. Rosenzweig is not a toxicologist, he stated that he regularly encounters cytotoxicity in his practice, including in women who have polypropylene mesh implants[.]" *Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at **5-6 (S.D. W. Va. May 5, 2015); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 707 (S.D. W. Va. 2014).

As a result, this Court "has considered Dr. Rosenzweig as a general causation expert [several] times in the past, and on each occasion [the Court has] admitted his general causation testimony on the properties of polypropylene mesh." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 565 (S.D. W. Va. 2014), *as amended* Oct. 29, 2014.

Dr. Rosenzweig is a pelvic-floor surgeon based in Chicago. Defendants have described Dr. Rosenzweig as a "[v]ery skilled pelvic floor surgeon,"[1] and Ethicon even invited Dr. Rosenzweig for special training in Belgium on how to implant the TVT-O device. (Rosenzweig General Wave 5 TVT Report ("TVT Report"), attached as Exhibit A, at 2).[2] Dr. Rosenzweig is an assistant professor of Obstetrics and Gynecology at Rush University Medical Center. Previously, he had fellowships at the State University of New York at Syracuse and at UCLA. He started a urogynecology program at the University of Illinois-Chicago, and he has performed more than one thousand surgeries in the pelvic floor, including more than 300 surgeries to address complications associated with synthetic mesh products. Dr. Rosenzweig has also published numerous articles and given numerous lectures on the treatments of urinary incontinence and pelvic organ prolapse. (*Id.* at 1-2).

Ethicon's attacks on Dr. Rosenzweig's opinions are nearly identical to the attacks from Wave 5, the first wave after Dr. Rosenzweig submitted his new reports. This response, therefore, is extremely similar to the Wave 5 response, but since there are minor differences, Plaintiffs will respond to Ethicon's actual arguments with an argument of our own, rather than simply adopting Wave 5 responses. Where Ethicon has adopted prior briefing—by incorporating its Wave 3 briefing—the Plaintiffs will do the same, as outlined below.

[1] Ethicon surgeon database, attached to Wave 1 response, Dkt. No. 2163-1, at Line 90.

[2] The Wave 5 Report is Dr. Rosenzweig's most up-to-date general report.

LEGAL STANDARDS

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). This aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

ARGUMENT

The Court should reject Ethicon's arguments for exclusion, as described below. The issues are addressed in the order presented by Ethicon.

I. The Court should deny Ethicon's first request for relief, which cites no rule, order, or other authority for limiting Dr. Rosenzweig's reliance on his prior expert reports and testimony.

Ethicon's first argument is difficult to address because it cites no rule, court order, or edict from case law that Dr. Rosenzweig supposedly has violated. Plaintiffs are also confused as to why Defendants never raised this issue until Wave 5, which was the point where Dr. Rosenzweig updated his opinions with new device-specific reports.

Throughout the Ethicon waves, Dr. Rosenzweig has referred to prior expert reports as his general report. For Wave 5, however, Dr. Rosenzweig submitted a series of updated, device-specific reports for six Ethicon devices. In addition, as noted in Ethicon's motion, he submitted a handful of prior reports on which he continues to rely, and he made statements generally adopting his prior opinions, as he has done in the past. (Def. Memo at 2-3). It makes little sense that Ethicon would only complain of Dr. Rosenzweig's adoption of prior reports when such adoption is done in addition to a wave-specific report.

Again, Ethicon cites no rule or Court order that Dr. Rosenzweig has supposedly violated. He has created new reports specifically for Wave 5, so those reports clearly reveal the opinions he intends to give at trial. But in this unique litigation, Dr. Rosenzweig has already given his opinions dozens of times in various ways—through prior reports, through deposition testimony, and through trial testimony. If he has revealed an opinion—or the rationale to support an opinion—in a prior report or in prior testimony, then the opinion (or rationale) should not be a surprise to Ethicon. The statements incorporating prior opinions and testimony are not intended to confuse anyone. They are simply intended to clarify that Dr. Rosenzweig continues to hold the opinions he has reiterated dozens of times, all of which Ethicon has repeatedly been made aware of, without the need for an absurdly long report reiterating all of Dr. Rosenzweig's prior reports and testimony.

II. As this Court has recognized, relevance is a highly case-specific issue. The Court should not issue a blanket exclusion of testimony about non-mesh alternatives when such alternatives may be relevant to design defect and negligence issues in a particular case.

The Court previously rejected Ethicon's next argument during Ethicon Wave 1, and the Court should not backtrack from its sound analysis. The issue is whether Dr. Rosenzweig's opinions regarding the safety of non-mesh procedures should be universally declared as

irrelevant to all trials in Wave 7—regardless of the state law that applies, and regardless of the evidence and arguments in a particular case. When faced with this issue previously, the Court wrote:

> *First*, Ethicon argues that Dr. Rosenzweig should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Ethicon does not challenge Dr. Rosenzweig's qualifications or the reliability of this expert testimony; instead, Ethicon challenges the relevance of this expert testimony. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I RESERVE ruling until trial.

In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., No. 2327, 2016 WL 4500765, at *3 (S.D. W. Va. Aug. 26, 2016). The Court should issue the same ruling in Wave 7.

A. <u>As recently held in the Northern District of Illinois, evidence of non-mesh alternatives is relevant to assessing the utility of Ethicon's products, and to counter Ethicon's assertions that its products are the "gold standard" for treating SUI.</u>

In Dr. Rosenzweig's reports, he discusses the safety and efficacy of the Burch colposuspension—his own preferred treatment for stress urinary incontinence ("SUI")—and also native tissue repair using pubovaginal slings or autologous facial slings. (*See, e.g.*, TVT Report, Ex. A, at pp. 7-10). In his reports, Dr. Rosenzweig opines that the debilitating complications caused by the TVT line of products outweigh the benefits of those devices. (*See id.* at 92-96). He further asserts that "[t]his is especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of these life changing complications." (*Id.* at 93).

This Court did exclude some evidence of alternative procedures in the *Mullins* consolidation, but that order was directed to a specific issue of West Virginia law—i.e., what could constitute a safer alternative design. The case was continued immediately after the ruling was issued, so the impact on the trial was never fully determined. The Court should now

conclude that even if an alternative procedure cannot be used as an alternative design, where an alternative design is required to make a *prima facie* case, such evidence is relevant to other aspects of Plaintiffs' claims.

In *Mullins*, this Court applied West Virginia law and held that "evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." *Mullins v. Johnson & Johnson*, No. 2:12-CV-02952, 2017 WL 711766, at *2 (S.D. W. Va. Feb. 23, 2017). The court also held that polypropylene sutures do not constitute a "product," such that they could serve as an alternative design. *Id.* at **2-3. The court had previously determined that West Virginia law required evidence of a safer alternative design to make a prima facie case for strict liability/defective design. Thus, the question as to the Burch procedure and pubovaginal slings was whether those alternatives could qualify as safer alternative designs to meet that prima facie requirement. *See id.* By contrast, the issue raised by Ethicon in its Wave 7 motion is whether such testimony is **relevant**.

A case that was remanded from this Court and proceeded to trial under Illinois law is instructive. Under Illinois law, as in many states, one consideration in determining whether a product is unreasonably dangerous—applying the risk-utility test—is "[t]he usefulness and desirability of the product—its utility to the user and to the public as a whole." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 260–61 (Ill. 2007). In *Calles*, the plaintiff explained that the availability of non-mesh alternatives bore directly on that inquiry—i.e., the product's utility to the user and to the public as a whole. The plaintiff further explained that this testimony was relevant to the question of negligence, under Illinois law. As in most states, the negligence issue under Illinois law is whether the manufacturer deviated from what a reasonable manufacturer would have done. *See Baltus v. Weaver Div. of Kidde & Co.*, 557 N.E.2d 580, 585–86 (Ill. App.

Ct. 1990). The plaintiff explained that in assessing whether Ethicon's conduct was reasonable, the jury needed to know whether Ethicon was bringing its mesh product onto a market that had no other options for the treatment of SUI, or whether there were already safe and effective treatments on the market.

The plaintiff also explained that Dr. Rosenzweig's testimony was relevant because Ethicon would claim that its TVT products represent the safest available treatment for SUI. In fact, Ethicon's experts regularly assert that the TVT products are the "gold standard" for the treatment of SUI. Such assertions, the plaintiff explained, would put into issue the question of whether the TVT products are, in fact, the safest and most effective treatment for SUI.

The court agreed and permitted Dr. Rosenzweig to opine about non-mesh alternatives to Ethicon's products. The court wrote that "the availability of other safe and effective procedures to treat the same condition is relevant and admissible, as plaintiffs contend, to show the utility of the defendants' product (factor 1)—a point not addressed in the other cases upon which defendants rely." *Herrera-Nevarez v. Ethicon, Inc.*, No. 12 C 2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017).[3] The court further agreed with the plaintiff "that this evidence is admissible to rebut defendants' contention that the TVT-O and similar products are the 'gold standard' for treating SUI." *Id.*

That reasoning explains why it would be inappropriate to issue the blanket exclusion sought by Ethicon. Without examining the particular state law at issue, and without examining the contentions made by Ethicon in a particular case, no court should exclude Dr. Rosenzweig's testimony on these points.

[3] The court's analysis was in reference to Dr. Daniel Elliott, but as the court wrote in addressing Dr. Rosenzweig's testimony immediately thereafter, the issue is exactly the same regardless of the expert involved.

Under Rule 401, the standard for relevance is not high. To be relevant, evidence must have "any tendency to make a fact more or less probable than it would be without the evidence," and the fact must be "of consequence in determining the action." Fed. R. Evid. 401(a)-(b). In the Wave 7 cases, Dr. Rosenzweig will explain that two other available treatments, the Burch procedure and pubovaginal slings, would have been safer than implanting mesh products, while being equally as effective. (*See, e.g.*, TVT Report at 92-96). As discussed in *Herrera-Nevarez*, such opinions are likely relevant, under a particular state's law, to whether Ethicon's mesh products are unreasonably dangerous, to whether Ethicon was negligent in designing them, and to rebut assertions by Ethicon that its products are the safest and most effective treatments for SUI.

B. Even if the Court excludes testimony about alternative procedures that do not utilize products, such exclusion should not apply to native tissue repair.

Arguing in the alternative, even if the Court concludes that an alternative treatment method must involve a "product" to be relevant, the Court should allow testimony about pubovaginal slings/native tissue repair.

While this Court in *Mullins* rejected the argument that polypropylene sutures in and of themselves could constitute a "product," pubovaginal slings—and other forms of native tissue repair—involve a substantial amount of material **in addition to** the polypropylene sutures that are used to attach the sling. The Court's *Mullins* order did not address this category of product.

Dr. Rosenzweig's TVT report explains pubovaginal slings as follows:

> The procedure involves placing a band of autologous, allograft, xenograft or synthetic material directly under the bladder neck (i.e., proximal urethra) or mid-urethra, which acts as physical support to prevent bladder neck and urethral descent during physical activity. This is brought up through the rectus fascia. The sling also may augment the resting urethral closure pressure with increases in intra-abdominal pressure.

(Rosenzweig TVT Report at 9). Thus, there is substantial additional material involved in a pubovaginal sling, in addition to whatever is used to hold it in place (which may or may not be a polypropylene suture).

Generally, pubovaginal slings use tissue from a human or animal cadaver to create the sling that is used to treat SUI. For instance, one company that produces such products is Coloplast Corp. In describing its product on its website, Coloplast writes:

> **Product description:** Axis dermis has omnidirectional fibers that give it consistent high tensile strength, and the network of collagen bundles interconnecting in every direction make implantation and ingrowth uniform. Axis is extracted only in large pieces from the lower back and the back of upper leg. This gives Axis consistency in quality and structure.

Coloplast: Axis, https://www.coloplast.us/Axis-en-us.aspx#section=product-description_3 (last visited March 21, 2018). As this example describes, pubovaginal slings such as allografts are alternative products to treat stress urinary incontinence, using natural material instead of synthetic polypropylene. They involve much more than sutures.

A pharmaceutical case from this Court held that a jury should decide whether the substitution of natural material for synthetic material constitutes an alternative design. *See Keffer v. Wyeth*, 791 F. Supp. 2d 539, 548-50 (S.D. W. Va. 2011). In *Keffer*, the issue involved a hormonal replacement therapy drug. *Id.* at 541. The plaintiffs believed that the drug was dangerous because of the synthetic progestin in the drug, and asserted that natural material—oral micronized progesterone—would have been a safer ingredient to use in the drug. *Id.* at 548. The defense argued that the use of a natural material created a different product altogether, and therefore could not be held up as a "safer alternative design." The court held that that was an issue for the jury to decide. *Id.* at 549.

The same reasoning should apply here. The jury should decide whether a product made primarily from native tissue can serve as a safer alternative to mesh products.

III. Dr. Rosenzweig should be permitted to testify about mesh-based safer alternative designs such as Ultrapro.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section I of Dkt. No. 2931.

IV. Dr. Rosenzweig should be permitted to criticize the cut of the TVT mesh.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section II of Dkt. No. 2931.

V. Dr. Rosenzweig should be permitted to give his warnings opinions.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section III of Dkt. No. 2931.

VI. Dr. Rosenzweig should again be permitted to testify about degradation and other mesh properties, including the cytotoxicity of the mesh.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section IV of Dkt. No. 2931.

VII. Dr. Rosenzweig is qualified by knowledge and experience to opine about product testing, and he should at least be able to opine about the <u>need</u> for testing.

In Section VII, Defendants discuss three topics. Dr. Rosenzweig is not asking for reconsideration of prior orders regarding adverse event reporting or training, so those issues are largely uncontested. However, the Court should not expand the scope of any rulings regarding adverse events, such that Dr. Rosenzweig would be unable to even mention adverse event reports and how such events may not have occurred had the Defendant actually performed testing. At times, he will rely on particular adverse event reports as evidence to support his opinions, as this Court has permitted in the past. *See Mathison v. Boston Sci. Corp.*, No. 2:13-CV-05851, 2015

WL 2124991, at *20 (S.D. W. Va. May 6, 2015) (denying motion to exclude IFU opinions that commented, *inter alia*, on adverse events not listed in the IFU).

Plaintiffs respectfully request that this Court reconsider its prior ruling that Dr. Rosenzweig is not qualified to opine about Ethicon's testing. Dr. Rosenzweig's opinions about the inadequacy of Ethicon's testing are the product of his expertise about the agents in the female vaginal area. As one example, Dr. Rosenzweig opines that Ethicon should have conducted testing to determine whether the polypropylene degrades. (Rosenzweig TVT Report, Ex. A, at 19). This opinion is a natural corollary to an opinion Dr. Rosenzweig has been permitted to give, that the mesh degrades in vivo. *See Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *5 (S.D. W. Va. May 5, 2015).

Dr. Rosenzweig is not merely relying on his clinical experience in opining about Ethicon's testing (or lack thereof). Rather, he also has substantial experience with testing genitourinary and pelvic medical devices, including the following:

- Dr. Rosenzweig was involved in the development of an Amnio-infusion catheter, and he helped to develop a randomized controlled trial ("RCT") to test infusion into the uterus, as compared with placing a sham single catheter.
- He worked with EMPI on testing the Innova electrical simulator designed to treat SUI, and he helped to design an RCT to test using a sham similar as compared to an active simulator.
- He was an investigator for a study for Lea Shield and Fem cap, both cervical cap contraceptives. The study was designed to choose the appropriate size to avoid pregnancy while also gaining FDA approval as over-the-counter drugs.

(Rosenzweig Affidavit, attached as Exhibit B, at ¶¶ 4-6).

Based on this experience, the Court should conclude that Dr. Rosenzweig is qualified to opine about product testing. Alternatively, even if the Court still believes that Dr. Rosenzweig is unqualified to opine as to the **adequacy** of Ethicon's testing, Dr. Rosenzweig has the experience and expertise to opine about whether testing to evaluate certain potential problems was necessary **at all**, based on the available information. Therefore, this Court should reject the request to issue a blanket exclusion of all opinions related to testing.

VIII. Dr. Rosenzweig will not opine about Defendants' marketing practices.

The Defendants' eighth issue is uncontested. The Court has previously excluded Dr. Rosenzweig from opining about Defendants' marketing practices, and Plaintiffs are not seeking reconsideration of that ruling at this time.

IX. Dr. Rosenzweig should be permitted to give his opinions about the Material Safety Data Sheet for polypropylene.

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section VIII of Dkt. No. 2931.

X. Other opinions

The Defendants adopted their Wave 3 briefing, and Plaintiffs hereby do the same, adopting the response contained in Section X of Dkt. No. 2931.

CONCLUSION

The Court should deny Ethicon's motion, except as to the issues conceded above.

Dated: March 21, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on March 21, 2018, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Thomas P. Cartmell
Attorney for Plaintiffs

INDEX OF EXHIBITS

Exhibit A: Bruce Rosenzweig General Wave 5 TVT Report

Exhibit B: Bruce Rosenzweig Affidavit